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K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER FAY, ZOHREH A	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/854,414
Filing Date: May 10, 2001
Appellant(s): HORN, GERALD

Thomas Basso
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 11, 2011 appealing from the Office action mailed January 14, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 74-77.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

4,443,441	Galin	03-1997
5,612,027	Galin et al.	04-1984

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-75 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Galin (U.S. Patent 4,443,441). Galin teaches the use of the claimed alpha1 antagonist, phentolamine as a miotic agent in a pharmaceutical formulation. See column 1, line 54 and claim 1. The above reference makes clear that the claimed composition is old and well known.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 74-77 are rejected less than 35 U.S.C. 103(a) as being unpatentable over Galin (US 4,443,441) in view of Galin et al. (5,612,027).

Galin (4,443,441) was discussed in the anticipation rejection. The primary reference differs from the claimed invention in the presence of an artificial tear. Galin et

al. teach the use of viscoelastic agents (artificial tear) in combination with mydriatic and miotic agents in ophthalmic formulation as old and well known. See column 2, lines 35-67 and column 3, lines 1-67. It would have been obvious to a person skilled in the art to add an artificial tear to the composition of primary reference motivated by the teachings of Galin et al., that the addition of such agents to mydriatic and miotic agents in ophthalmic field as old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed compound phentolamine at the claimed concentrations in an ophthalmic formulation, and the other relates to the use of artificial tear as a carrier in ophthalmic formulations as old and well known. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 74-77 are properly rejected under 35 U.S.C. 103 (a).

Double Patenting

Claims 74-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33-36 of copending Application No. 10/799,299. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

(10) Response to Argument

Appellant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Appellant in his remarks argues that Galin is directed to six

alpha-adrenergic blocking agents, the preferred agent and the only working example is directed to thymoxamine, and thus Galin fails to recognize the improved benefit of the ophthalmic night vision formulation with phentolamine. The arguments are noted. Appellant's attention is directed to claim 1 of Galin, which claims phentolamine as one alpha-adrenergic blocking agent for ophthalmic use. Therefore, phentolamine has been disclosed and claimed by Galin. Appellant also refers to the data in the specification in order to show the advantages of phentolamine on vision in dim light in comparison to other alpha-adrenergic blocking formulation. It is the examiner's position that such data are not commensurate in scope with the claimed language. Such data use one concentration of phentolamine and one concentration of other alpha-adrenergic blocking agents. Finally, in the absence of any difference between the claimed composition and the prior art compositions, it is expected that the prior art composition also have the same benefits as the claimed composition. Applicant's remarks regarding the Galin et al. have been noted. Appellant in his remarks argues that the viscous composition of Galin et al. being used for the treatment of anterior chamber of the eye at the concentrations of 10 mg/ml and 30mg/ml is different than the viscoelastic artificial tear of the present invention. It is the examiner's position that the prior art uses the viscoelastic agents within the claimed concentrations in combination with miotic agents. Therefore, such reference makes clear that the use of viscoelastic agents in combination with miotic agents in ophthalmic formulations as old and well known.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Zohreh A Fay/

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